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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,396	11/28/2000	James F. Young	10271-007-999	8214

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PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 100362711

EXAMINER
BROWN, STACY S

ART UNIT	PAPER NUMBER
1648	15

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,396	YOUNG ET AL.	
	Examiner	Art Unit	
	Stacy S Brown	1648	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *73,74,85-110,180,181,186,187,189-191 and 200-230* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *73,74,85-110,180,181,186,187,189-191 and 200-230* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 November 2000* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's amendment is acknowledged and entered. Claims 73-74, 85-110, 180-181, 186-187, 189-191 and 200-230 are pending and examined. The objection to the specification and claims are withdrawn in view of Applicant's amendments.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 200-230 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to methods of preventing, treating and ameliorating one or more symptoms of RSV, comprising the administration of palivizumab. The claims recite specific amounts of serum titers maintained after administration.

The breadth of the claims is reasonable, encompassing specific titers and days after which the titer is maintained after administration. The nature of the invention is passive immunization with a known antibody (palivizumab) that treats RSV. The state of the prior art is evidenced by MedImmune (of record) which discloses that the recommended dosage of palivizumab is 15 mg/kg. One of ordinary skill in the art would predict that the administration of more than 15 mg/kg would result in higher serum titer. The amount of guidance provided for obtaining the titer levels is found in the specification, which discloses the specific amounts (page 23).

However, there are no working examples showing that lower doses of palivizumab actually resulted in higher serum titer. Applicant is invited to point to evidence in the specification that lower doses of palivizumab are likely to result in higher serum titer.

3. The rejection of claims 85-110 under 35 U.S.C. 112, second paragraph is maintained for reasons of record, with regard to "therapeutically effective". Applicant's arguments have been carefully considered but fail to persuade. The meaning of "therapeutically effective" is defined according to page 30, lines 12-15 with regard to cotton rats. However, for other mammals, the definition of "therapeutically effective" is not clear. The specification, page 30, merely discloses "therapeutically effective serum titer" indicate amounts that reduce the severity, duration and/or symptoms associated with RSV infection. However, it is unclear what endpoints indicate the reduction of severity, reduction of duration and reduction of symptoms associated with RSV.

Claim Rejections - 35 USC § 102

4. The rejection of claim 74 under 35 U.S.C. 102(b) as anticipated by Brams et al (5,811,524) is withdrawn in view of Applicant's amendments.

Claim 74 is rejected under 35 U.S.C. 102(b) as being anticipated by Johnson *et al* (*J. Infect. Dis.*, 1997, 176:1215-1224, reference CC of IDS). Claim 74 is drawn to a pharmaceutical composition adapted for pulmonary delivery comprising palivizumab or fragments thereof that immunospecifically bind to one or more RSV antigens and a suitable carrier. Johnson teaches a humanized monoclonal antibody (MEDI-493), palivizumab, that binds F glycoprotein of RSV. These antibodies are administered intranasally. As Applicant points out, the antibodies are only

administered to cotton rats. However, claim 74 does not characterize the recipient of the antibodies.

Claim Rejections - 35 USC § 103

5. In the Office action mailed March 26, 2002, claims 1-72 and 85-199 were rejected under 35 U.S.C. 103(a) as being unpatentable over Brams (5,811,524) or Johnson (reference CC) in view of MedImmune (package insert, 1999), Johnson (reference AF) and Lam (reference CG). Claims 73-74 should have been included in the rejection, but they were omitted by a typo. The claims were discussed in the rejection on pages 6-7 of the office action, as evidenced by the incorporation of the Lam reference.

Claims 73 and 85-94 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (reference CC) in view of Lam (reference CG), for reasons of record. Applicants mainly argue that Johnson (CC) fails to teach the administration of palivizumab to human subjects. In response, it should be noted that claims 73-74 and 85-94 do not characterize the subject as human; claims 95-110 recite "human".

Claims 95-110, 180-181, 186-187 and 189-191 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (reference CC) in view of MedImmune (package insert, 1999) and Lam (reference CG), for reasons of record. Applicants mainly argue that Johnson (CC) fails to teach the administration of palivizumab to human subjects. MedImmune teaches the administration of MEDI-493 (palivizumab) to infants (see abstract). It would have been obvious to administer Johnson's antibodies in the manner in which MedImmune describes since the antibodies are the same (palivizumab).

Conclusion

6. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday and alternate Wednesdays from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stacy S. Brown
December 2, 2002

JAMES HOUSEL 12/2/02
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600